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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-451]

Schedules of Controlled Substances: Placement of MT-45 into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration places the substance MT-45 (Systematic IUPAC Name: 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine), including its salts, isomers, and salts of isomers into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act and is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1961. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle, MT-45.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201(d)(1) of the Controlled Substances Act (CSA) (21 U.S.C. 811(d)(1)) states that, if control of a substance is required “by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section [811(a)] or section 812(b) ... and without regard to the procedures prescribed by subsections (a) and (b) of this section [21 USC 811(a) and (b)]....” If a substance is added to one of the schedules of the Single Convention on Narcotic Drugs, 1961 (“Single Convention”), then, in accordance with article 3, paragraph 7 of the Convention, as a signatory Member State, the United States is obligated to control the substance under its national drug control legislation, the CSA. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

On May 17, 2016, the Secretary-General of the United Nations advised the Secretary of State of the United States, by letter, that during the 59th session of the Commission on Narcotic Drugs, MT-45 was added to schedule I of the Single Convention. This letter was prompted by a decision at the 59th session of the Commission on Narcotic Drugs in March 2016 to schedule MT-45 under schedule I of the Single Convention. As a signatory Member State to the Single Convention, the United States is obligated to

control MT-45 under its national drug control legislation, the CSA, in the schedule deemed most appropriate to carry out its international obligations. 21 U.S.C. 811(d)(1).

MT-45

MT-45 is an opioid analgesic drug with pharmacological effects similar to morphine. MT-45 was demonstrated to produce physical dependence in mice. This compound is a piperazine derivative and is structurally unrelated to most other opioids. There are two enantiomers of MT-45 (*R* and *S*). Both enantiomers bind to opioid receptors, however (*S*)-(+)-MT-45 binds with a greater affinity than that of (*R*)-(-)-MT-45. In functional studies, (*S*)-(+)-MT-45 has an analgesic effect similar to morphine. In comparison, the analgesic effect of (*R*)-(-)-MT-45 is low.

Starting in 2013, MT-45 began appearing on the internet for sale as a ‘legal’ opioid. Recent reports from Japan have indicated that MT-45 is present in herbal and chemical mixtures containing synthetic cannabinoids and/or synthetic cathinones. Deaths associated with MT-45 abuse have occurred in the United States and in Europe. In addition, there have been at least 13 non-fatal overdoses associated with abuse of MT-45. There are no published studies as to the safety of MT-45 for human use. The DEA is not aware of any claims or any medical or scientific literature suggesting that MT-45 has a currently accepted medical use in treatment in the United States. Accordingly, the DEA has not requested that the Department of Health and Human Services (HHS) conduct a scientific and medical evaluation of the substance’s medical utility. Furthermore, the DEA is not required under 21 U.S.C. 811(d)(1) to make any findings required by 21 U.S.C. 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 U.S.C. 811(a) and (b). Therefore, consistent with the framework of 21 U.S.C. 811(d), the

DEA concludes that MT-45 has no currently accepted medical use in treatment in the United States and is most appropriately placed in schedule I of the CSA.

Conclusion

In order to meet the obligations of the United States under the Single Convention on Narcotic Drugs, 1961, and because MT-45 has no currently accepted medical use in treatment in the United States, the Administrator of the Drug Enforcement Administration has determined that this substance should be placed in schedule I of the Controlled Substances Act.

Requirements for Handling

Upon the effective date of this final order, MT-45 will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, engagement in research, and conduct of instructional activities, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, MT-45 must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Any person who currently handles MT-45, and is not registered with the DEA, must submit an application for registration and may not continue to handle MT-45 as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], unless the DEA has approved that

application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle MT-45 must surrender all quantities of currently held MT-45, or may transfer all quantities of currently held MT-45 to a person registered with the DEA on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] in accordance with all applicable federal, state, local, and tribal laws. As of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], MT-45 must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* MT-45 will be subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

4. *Labeling and packaging.* As of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], all labels, labeling, and packaging for commercial containers of MT-45 must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of MT-45 on the effective date of this order must take an inventory of all stocks of this substance on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. After the initial inventory, every DEA registrant must take an inventory of

all MT-45 on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to MT-45 pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, and 1312, and 1317 as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

7. *Reports.* All DEA registrants who manufacture or distribute MT-45 must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

8. *Order Forms.* All DEA registrants who distribute MT-45 must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

9. *Importation and Exportation.* All importation and exportation of MT-45 must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

10. *Quota.* Only DEA registered manufacturers may manufacture MT-45 in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

11. *Liability.* Any activity involving MT-45 not authorized by, or in violation of the CSA, occurring as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Order 12866, Regulatory Planning and Review

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of Executive Order 13132. The action does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This action does not have tribal implications warranting the application of Executive Order 13175. The action does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties, conventions, or protocols.

21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty,

convention, or protocol, the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions.

To the extent that 21 U.S.C. 811(d)(1) directs that if control is required by the United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, scheduling actions shall be issued by order (as compared to scheduling pursuant to 21 U.S.C. 811(a) by rule), the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute “rule making” under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 21 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States given that this action is being done in accordance with 21 U.S.C. 811(d)(1)’s requirement that such action be taken to comply with the United States obligations under the specified international agreement.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. An agency may not conduct or sponsor,

and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This order will not result in: “an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign based enterprises in domestic and export markets.” However, pursuant to the CRA, the DEA has submitted a copy of this order to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. Amend § 1308.11 by:

- a. Redesignating paragraphs (b)(40) through (57) as (b)(41) through (58);
- b. Adding new paragraph (b)(40).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(40) MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine).....(9560)

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Dated: December 5, 2017.

Robert W. Patterson,
Acting Administrator.

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